Statistical Modeling of Tibial Trays Reduces the Risk of Malrotation in TKR

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Introduction: Malrotation of the tibial component is frequently cited as the cause of pain, effusions and soft-tissue tightness following TKA. Correct rotational placement of the tibial component is especially challenging, primarily because the anatomic landmarks on the tibia are highly variable and are poorly correlated with the motion axis of the knee. This has led to a proliferation of tibial implant designs that differ in shape (symmetric vs. asymmetric designs) and in the number of sizes (7 to 18), to “match” the shape of the tibial resection surface without cortical overhang. As symmetric trays provide better fit when they are placed in internal rotation, more recent approach has been to develop anatomic profiles using statistical analysis of the variation of shape and size of the human tibia (anatomic design) using correctly aligned axis systems. Although this approach has theoretical advantages, it is not known whether it leads to measurable benefits in clinical practice. This study was performed to answer the questions:
1. Have any of these modifications in the design of tibial components translated to benefits in clinical practice?
2. Does the design of the implant affect the results of surgeons and trainees equally?

Methods: CAD models of each size of tibial trays of 7 popular TKA designs were prepared by reverse engineering. Four of the designs were symmetric (medial -lateral) in profile, two were asymmetric (fixed geometric shapes), and one was anatomic (shapes derived by statistical analysis of large bone populations). Computer models of ten tibias (7 males, 3 females), were selected from a large anatomic collection to span the normal anatomical variation in the shape and size of the tibia. The proximal surface of each computer model was resected perpendicular to the canal axis, 5mm distal to the medial plateau, with a posterior slope of 5 degrees. Thirty-one surgeons (16 experienced joint surgeons and 15 orthopedic trainees) each performed 70 virtual fitting exercises by selecting the size and position of each design providing the best fit to each resection surface. The final composite model of each tray positioned on each tibia was analyzed to determine: (i) the rotational alignment of the tray with respect to the neutral axis defined by Berger et al using the axis joining the center of the resection surface and the tibial tubercle, (ii) tibial coverage, defined as the percentage of the area of the resection surface covered by the tibial component, and (iii) cortical overhang/under-coverage, measured in seven anatomic regions encompassing the circumference of the tray. Differences between each of these parameters were statistically evaluated as a function of study participant (surgeon/trainee) and tray design (symmetric/asymmetric/anatomic) using ANOVA and Fisher’s PLSD test for post-hoc comparisons between groups.

Results: A total of 2,170 virtual implantations were performed as part of this study. Across all participants and component designs, the tibial components were placed in an average of 5.29±0.07° of external rotation relative to the Berger axis (Figure 1). There was no difference between the average rotation of the symmetric and asymmetric designs (5.04±0.09° vs. 5.07±0.12°) (p=0.385). However, the anatomic components were placed in 6.71±0.19° of external rotation, significantly more than the symmetric and asymmetric designs (p< 0.0001). For all tray designs, surgeons placed components in approximately 2.3° more external rotation than the trainees, independent of the implant design (p<.0001 for all comparisons). Overall, 147 (6.8%) trays were placed in internal rotation, by 8 surgeons (0.7%), and 14 trainees (13.2%; p=0.0001) (Figure 2). There was no significant difference in the incidence of malrotation of the symmetric vs asymmetric components (7.8±0.8% vs. 6.8±1.0%; p=0.385). These values were approximately three times larger than seen with the anatomic design (2.6±0.9%; p=0.0010, 0.0164). The influence of tray design was most dramatic in the trainee group, where 15.0% of symmetric and 13.7% of asymmetric components were internally rotated, compared to only 5.3% of the anatomic design (p=0.0018, 0.0138). Tibial coverage was 75.9±0.1% overall, and was slightly smaller with the symmetric designs (74.2±0.1%), compared to both the asymmetric (77.8±0.2%; p<0.0001), and anatomic components (78.9±0.0%; p<0.0001). Differences in tibial coverage achieved by trainees and surgeons were minimal (74.7±4.1% vs. 73.8±3.9%). The asymmetric and anatomic designs left significantly less uncovered bone in all regions (p<0.0001), except for the antero-medial corner.

Discussion: 1. Our study demonstrates that the risk of component mal-rotation is strongly affected by implant design and surgical experience.
2. Overall, there was no significant difference between the performance of asymmetric and symmetric components in terms of any of the parameters examined. Conversely, components of the anatomic design were rarely placed in internal rotation and...
had slightly greater tibial coverage than any of the other implants studied.
3. Trainees placed trays of all designs in less external rotation than experienced joint surgeons, and prioritized coverage of the exposed tibial surface, especially when positioning symmetric components. This lead to a dramatic increase in mal-rotated components for only a small gain in tibial coverage.

**Significance:** Correct rotational placement of the tibial component is especially challenging, primarily because the anatomic landmarks on the tibia are highly variable and are poorly correlated with the motion axis of the knee. This study investigates the effects of tibial implant shape on component placement for both surgeons and trainees.

**Acknowledgments:**

**References:**
- Figure 1 - Distribution of rotational values for each tray design, ordered from greatest internal rotation to greatest external rotation
- Figure 2 - Incidence of internal rotation for surgeons and trainees as a function of tibial tray design.